committee involved. The notice of the change shall be reflected in sponsor, investigator, and institutional review committee records and in reports under §813.153(c) and shall be reviewed by the institutional review committee in the regular course of business.

(b) When a change in or deviation from the investigational plan is necessary to eliminate or reduce an apparent immediate hazard to the safety of a human subject who is already participating in the investigational study, the investigator is not required to comply with the prior approval requirements of paragraph (a) of this section. The investigator shall instead notify any institutional review committee and the sponsor, who shall notify the Food and Drug Administration of the change or deviation and the justification therefor as soon as possible but in no event later than 5 days after such change or deviation is implemented as required by §813.39(b)(2).

§813.107 Control over intraocular lenses.

(a) An investigator shall only permit the lens to be used for administration to, or use involving, subjects who are under his personal supervision or under the supervision of another investigator who is responsible to him and who is named by the investigator in his signed statement undertaking the obligations of an investigator under §813.43(b). An investigator shall not supply the lens to any other person for administration to, or use involving, subjects or for any other purpose, without the prior authorization of the sponsor.

(b) An investigator shall return to the sponsor any reusable or unused supply of the lens upon direction of the sponsor, or upon suspension, termination, completion, discontinuance of, or withdrawal of the exemption for, the investigational study. The sponsor may direct or agree to alternative disposition of the lens such as destruction or use in animal or in vitro experiments.

§813.119 Disqualification of a clinical investigator.

(a) *Purposes.* The purpose(s) of disqualification of an investigator who has violated the regulations set forth in this part may be one or both of the following:

(1) To preclude the investigator from conducting clinical investigations subject to requirements under the act for prior submission to the Food and Drug Administration until such time as it becomes likely that he will abide by such regulations or that such violations will not recur. The determination to disqualify an investigator does not necessarily consitute a finding or recommendation that the investigator is not qualified to practice or teach medicine or should be subject to other sanctions by other persons such as licensing boards or employers.

(2) To exclude the consideration of any clinical investigations or portions thereof in support of applications for an investigational exemption or for premarket approval from the Food and Drug Administration, which investigations have been conducted in whole or in part by the investigator, until such time as it becomes likely that he will abide by such regulations or that such violations will not recur or that it can be adequately demonstrated that such violations did not occur during or affect the validity or acceptability of a particular investigation or investigations. The determinations that a clinical investigation may not be considered in support of an application for exemption or premarket approval does not, however, relieve the applicant for such an application of any obligation under any other applicable regulation to submit the results of the investigation to the Food and Drug Administration.

(b) *Grounds for disqualification.* The Commissioner may disqualify an investigator upon finding all the following:

(1) The investigator violated any of the regulations set forth in this part;

(2) The violation or violations adversely affected the validity of the clinical investigation, the rights of the human subjects, and/or the safety of the subjects; and

(3) Other lesser regulatory actions, e.g., warnings or rejection of data from individual investigations, have not been or will probably not be adequate to assure that the investigator will comply with such regulations in the future.